

THREADFORM FOR MEDICAL IMPLANT CLOSUREBackground of the Invention

1 The present invention is directed to a threadform for
2 use in threadedly joining together two elements and, in
3 particular, to a threadform for joining together medical
4 implants. The threadform includes a leading surface and a
5 trailing surface, both of which slant rearwardly and away
6 from the direction of advancement from an inner edge to an
7 outer edge thereof.

8 Medical implants present a number of problems to both
9 surgeons installing implants and to engineers designing
10 them. It is always desirable to have the implant be strong
11 and unlikely to fail or break during usage. It is also
12 desirable for the implant to be as small and lightweight as
13 possible so that it is less intrusive on the patient. These
14 are normally conflicting goals, and often difficult to
15 resolve.

16 One particular type of implant presents special
17 problems. In particular, spinal bone screws, hooks, etc.
18 are used in many types of back surgery for repair of injury,
19 disease or congenital defect. For example, spinal bone

1 screws of this type are designed to have one end that
2 inserts threadably into a vertebra and a head at an opposite
3 end thereof. The head is designed to receive a rod or rod-
4 like member which is then both captured in the head and
5 locked in the head to prevent relative movement between the
6 various elements subsequent to installation.

7 There are two different major types of bone screws and
8 similar devices. The types are closed head and open head.

9 The closed head devices are highly effective at capturing
10 the rod since the rod is threaded through an opening in the
11 head. Unfortunately, closed head devices are very difficult
12 to work with in actual surgery as the spine is curved and
13 the rods are also curved in order to follow the spine.
14 Consequently, the more heads that the rod must pass through,
15 the more difficult it is to thread it.

16 The second type of head is an open head wherein a
17 channel is formed in the head and the rod is simply laid in
18 an open channel. The channel is then closed with a closure.
19 The open headed bone screws and related devices are much
20 easier to use and in some situations must be used over the
21 closed headed devices.

22 While the open headed devices are often necessary and
23 often preferred for usage, there is a significant problem

1 associated with them. That is, the open headed devices
2 conventionally have two upstanding arms that are on opposite
3 sides of a channel that receives the rod member. In order
4 to lock the rod member in place, significant forces must be
5 exerted on a relatively small device. The forces are
6 required to provide enough torque to insure that the rod
7 member is locked in place relative to the bone screw so that
8 it does not move axially or rotationally therein. This
9 typically requires torques on the order of 100 inch pounds.

10 Because the bone screws, hooks and the like are
11 relatively small, the arms that extend upwardly at the head
12 can be easily bent by radially outward directed forces due
13 to the application of substantial forces required to lock
14 the rod member. Historically, early closures were simple
15 plugs that were threaded and which screwed into mating
16 threads on the inside of each of the arms. However,
17 conventionally threaded plugs push the arms radially outward
18 upon the application of a significant amount of torque which
19 ends up bending the arms sufficiently to allow the threads
20 to disengage and the closure to fail. To counter this
21 various engineering techniques were applied to allow the
22 head to resist the spreading force. For example, the arms
23 were significantly strengthened by increasing the width of

1 the arms by many times. This had the unfortunate effect of
2 substantially increasing the weight and the size of the
3 implant, which was undesirable. Many prior art devices have
4 also attempted to provide rings or some other type of
5 structure that goes about the outside of the arms to better
6 hold the arms in place while the center plug is installed.
7 This additional structure has typically caused the locking
8 strength of the plug being reduced which is undesirable.

9 Also, the additional elements are unfavorable from a point
10 of view of implants, as it typically desirable to maintain
11 the number parts associated with the implants at a minimum.

12 Consequently, a lightweight and low profile closure
13 plug was desired that resists spreading of the arms while
14 also not requiring additional elements that circle around
15 the outside of the arms so as to hold the arms in place.

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17 Summary of the Invention

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19 A threaded closure for use in conjunction with an open
20 headed medical implant wherein the thread associated with
21 the closure exerts forces that draw the arms radially inward
22 toward the closure rather than outward from the closure
23 during installation. In this manner the arms do not spread

1 substantially during installation of the closure under the
2 torque required to lock a rod member within the head of the
3 implant.

4 The thread is preferably helically wound about a
5 cylindrical outer surface of the closure and preferably has
6 an inner radius and outer radius that remain constant over
7 substantially the entire length of the thread. The thread
8 has both a leading surface and a trailing surface that have
9 inner edges that are spaced from one another. Preferably
10 the outer edges of the leading and trailing surfaces are in
11 close proximity to one another such that the thread has a
12 generally obtuse triangular shaped cross-section, with minor
13 reduction or rounding at the outer tip.

14 Whereas in V-shaped thread forms, the leading surface
15 slopes rearwardly from the inner edge and the trailing
16 surface slopes forwardly from the leading edge, and in
17 buttress-type threads, the leading surface slopes rearwardly
18 from the inner edge and the trailing surface slopes slightly
19 forwardly or has no slope, the thread of the present
20 invention is such that both the leading surface and the
21 trailing surface slope rearwardly with respect to the
22 direction of advancement from the respective inner edges to
23 outer edges thereof. That is, the intersections of a plane

1 passing through an axis of rotation of the closure with the
2 leading and trailing surfaces both slope rearwardly from the
3 respective inner edges of the leading and trailing surfaces
4 relative to the direction of advancement of the closure in
5 the open-headed implant.

6 The inner facing surfaces of the arms are likewise
7 threaded with a mating threadform that is sized and shaped
8 to mate with the thread on the closure. The mating
9 threadform on the implant arms is discontinuous between the
10 arms.

11 Because of the configuration of the thread on the
12 closure and the mating thread on the arms, forces applied to
13 the closure, during installation of the closure between the
14 arms, produce a reactive axial force on the arms of the
15 implant, but also produce a somewhat inward force thereon.
16 Therefore, the arms are urged toward the closure during
17 installation rather than away from the closure during
18 installation. In this manner the thread and mating thread
19 function in a gripping manner between the opposed elements
20 to hold them together, rather than force them apart.

1 Objects and Advantages of the Invention
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3 Therefore, the objects of the present invention are: to
4 provide a closure for an open headed lightweight and low
5 profile medical implant wherein the implant has a pair of
6 spaced arms and the closure closes between the arms; to
7 provide such a closure which is threaded and which does not
8 substantially space the arms during insertion, so as to
9 reduce the likelihood of failure of the implant and closure
10 system during use; to provide such a closure having a
11 threadform that includes leading and trailing surfaces, both
12 of which surfaces slope rearwardly from inner edges to outer
13 edges thereof; to provide such a closure wherein the inner
14 edges of both the trailing and leading surfaces have
15 substantially constant radius over an entire length of the
16 thread; to provide such a closure which can be installed at
17 comparatively high torques so as to lock a rod member in the
18 open head of the implant; and to provide such a closure and
19 implant that are relatively easy to use and especially well
20 adapted for the intended usage thereof.

21 Other objects and advantages of this invention will
22 become apparent from the following description taken in
23 conjunction with the accompanying drawings wherein are set

1 forth, by way of illustration and example, certain
2 embodiments of this invention.

3 The drawings constitute a part of this specification
4 and include exemplary embodiments of the present invention
5 and illustrate various objects and features thereof.

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7 Brief Description of the Drawings

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9 Figure 1 is an exploded perspective view of an open
10 headed bone screw, rod and closure for the bone screw in
11 accordance with the present invention.

12 Figure 2 is a fragmentary side elevational view of the
13 bone screw, rod and closure installed in the bone screw.

14 Figure 3 is a fragmentary cross-sectional view of the
15 closure, taken along line 3-3 of Fig. 1.

16 Figure 4 is a highly enlarged and fragmentary side
17 elevational view of the bone screw, rod and closure with a
18 right hand arm of the bone screw shown in phantom lines in
19 order to better illustrate features of the closure.

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1 Detailed Description of the Invention

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3 As required, detailed embodiments of the present
4 invention are disclosed herein; however, it is to be
5 understood that the disclosed embodiments are merely
6 exemplary of the invention, which may be embodied in various
7 forms. Therefore, specific structural and functional
8 details disclosed herein are not to be interpreted as
9 limiting, but merely as a basis for the claims and as a
10 representative basis for teaching one skilled in the art to
11 variously employ the present invention in virtually any
12 appropriately detailed structure.

13 The reference 1 generally indicates a thread form or
14 thread in accordance with the present invention that is
15 located on a medical implant closure 5 that is used in
16 conjunction with a rod member 6 and an open headed medical
17 implant 7.

18 Describing the elements in reverse order, the
19 illustrated open headed medical implant 7 is a bone screw
20 for use in spinal surgery. The implant 7 includes a shank
21 11 having a bone engaging and implantation thread 12
22 thereon. The implant 7 also includes an open head 14. The
23 head 14 is U-shaped having a base 16 and a pair of

1 upstanding spaced arms 17 and 18. The arms 17 and 18 are
2 spaced by a channel 20 having a seat 21 at the bottom
3 thereof. The arms 17 and 18 have facing surfaces 24 and 25
4 that are sides of the channel 20. Each of the surfaces 24
5 and 25 have facing threaded sections 28 and 29 respectively.

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7 While the medical implant 7 shown here in is an open
8 headed bone screw, it is foreseen that the present invention
9 can be easily used and adapted with other types of open
10 headed implants such as hooks and the like.

11 *16* ~~The rod member 6 is typically simply an elongate~~
12 *16* ~~cylindrical rod which may be bent by benders to conform with~~
13 ~~the desired curvature of the spine. The rod member may be~~
14 ~~smooth or knurled. The rod member 6 may also include other~~
15 ~~types of similar structures such as connectors having a~~
16 ~~cylindrical or rod like nipple associated therewith for~~
17 ~~insertion into the bone screw head 14.~~

18 *22* ~~The illustrated closure 5 is a cylindrical shaped plug~~
19 ~~having a generally cylindrical shaped radially outer surface~~
20 ~~42, a flat bottom 33 and a flat top 34. The closure 5 has~~
21 ~~an axis of rotation, generally indicated by the reference~~
22 ~~numeral A. The axis of rotation A is at the radial center~~
23 ~~of the closure 5. A bore 37 that is co-axial with the axis~~

1 of rotation A extends through the top 34 and partially
2 though the closure 5. The bore 37 is polyfaceted so as to
3 have a hexagonal cross section such that closure 5 can be
4 installed or removed with an allen type wrench that fits the
5 bore 37.

6 Although a particular closure 5 has been illustrated
7 herein, it is foreseen that the invention can be used in
8 conjunction with plugs and set screws of various types and
9 configurations. For example, the closure 5 may include a
10 break off head for insertion and various types of structure
11 for removal, as opposed to the bore 37. The closure 5 may
12 also include structure to assist in engaging and securing
13 the rod member 6, such as a depending point, a roughened
14 under surface, or a cutting ring. Finally, although the
15 closure of the present invention is illustrated in use in
16 conjunction with an open headed implant, it is foreseen that
17 the closure 5 could be utilized in conjuncture with closed
18 bores, either as a plug or set screw.

19 *Hand A4* The thread 1 winds about the outer surface 32 of the
20 closure 5 in a generally helical pattern or configuration,
21 which is typical of threads and can have various pitches, be
22 counterclockwise advanced or vary in most of the way that
23 conventional threads vary. The thread 1 has a leading

1 surface 40 and a trailing surface 41. As used herein the
2 terms leading trailing refer to the direction of advancement
3 of the closure 5 when used to close the implant 7 which is
4 downward or in the direction of the rod member 6 in figure
5 4. In the illustrated embodiment, advancement is produced
6 by clockwise rotation. The leading surface 40 has an inner
7 edge 44 and an outer edge 45. The trailing surface 41 also
8 has an inner edge 48 and an outer edge 49.

9 *With reference to Figure 3, the leading surface inner*
10 *edge 44 and trailing surface inner edge 48 are substantially*
11 *spaced. Both the leading surface inner edge 44 and trailing*
12 *surface inner edge 48 have substantially constant radius*
13 *with respect to the axis of rotation A, preferably*
14 *throughout the length of the thread 1 and at least*
15 *throughout substantially most of the thread 1. The leading*
16 *surface outer edge 45 and trailing surface outer edge 49 are*
17 *closely spaced relative to one another and may be slightly*
18 *relieved as shown so as to have a slight connecting wall 50*
19 *that decreases the sharpness of the thread 1 and increases*
20 *the strength thereof. As can be seen in Figure 3, the*
21 *general shape of the cross section of the thread 1 is that*
22 *of a obtuse triangle with the outer sharpened edge slightly*
23 *reduced. It can also be seen that the intersection of the*

1 leading surface 40 and the trailing surface 41 with a plane
2 passing through the axis of rotation A which is essentially
3 what is shown in the front or closest surface shown in
4 Figure 3 both slope rearwardly, as indicated by the arrow
5 shown Figure 3 from inner edges 44 and 48 to outer edges 45
6 and 49 thereof.

7 The angle indicated by the reference numeral B is
8 between the intersection D of a plane passing through the
9 axis of rotation A and the leading surface 40 and a radius
10 perpendicular to the axis of rotation A. The angle
11 indicated by the reference numeral C is between the
12 intersection E of a plane passing through the axis of
13 rotation A and the trailing surface 41 and a radius
14 perpendicular to the axis of rotation A. The angle B is
15 substantially greater than the angle C. The angle C will
16 normally be between about 1 and 45° with the preferred angle
17 being between 5° and 20° and with the most preferred angle
18 being between 7 to 15°. Greater angles than 45° may
19 be utilized, but the thread decreases in strength as the
20 angle C increases which increases the likelihood that the
21 thread may break in use. The key feature of the trailing
22 surface 41 is that the surface 41 slopes rearwardly from
23 inside to outside. The angle B will vary with desired

1 thread strength and width of wall 50, but will always be
2 greater than angle C. Preferably the angle B is in the
3 range from 30° to 70° and it is preferred that the angle B be
4 in the range from 40° to 50°. In the illustrated embodiment
5 angle C is approximately 45° and angle B is approximately
6 15°.

7 As is best seen in Figure 4, the threaded sections 28
8 and 29 of the arms 17 and 18 respectively are provided with
9 a threadform 53 that is sized and shaped to threadedly
10 receive the thread 1. The threadform 53 is discontinuous,
11 as it extends over the threaded sections 28 and 29. The
12 threadform 53 has a first surface 55 that abuts against the
13 leading surface 40 and a second surface 56 that abuts
14 against the trailing surface 41 during use. It is noted that
15 as torque is applied to closure 5 in a clockwise manner so
16 as to advance the closure 5 in the implant 7, the trailing
17 surface 41 engages and pushes against the second surface 56
18 associated with implant 7. The force exerted on the closure
19 5 by this process is countered by a reactive force acting on
20 the implant 7 that has a first component that is axial, that
21 is parallel to the axis of rotation of the closure 5, and
22 second component that has a radial inward vector, that is
23 toward the axis of rotation of the closure 5. The surfaces

1 40 and 41 are non parallel to each other.

2 *Inv. No.* It is to be understood that while certain forms of the
3 present invention have been illustrated and described
4 herein, it is not to be limited to the specific forms or
5 arrangement of parts described and shown.